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JUL 31 2002

James Meschino, D.C., M.S.  
President  
Nutra Therapeutics International  
40 East Main Street  
Suite 168  
Newark, Delaware 19711

Dear Dr. Meschino:

This is in response to your letter of July 18, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Nutra Therapeutics International is making the following claims, among others, for the following products:

**Glucosamine Joint Formula**

- "...natural anti-inflammatory agents that rebuild cartilage and control the low-grade inflammation of osteoarthritis and joint injuries"
- "...block the further destruction of osteoarthritic joints and regenerate damaged joint cartilage"
- "...help reduce the swelling and inflammation associated with chronic osteoarthritis and related joint injuries where cartilage damage is present, such as sports injuries"
- "Advanced Formula for Relief and Repair of Arthritis and Cartilage Damage"
- "With Anti-Inflammatory Herbs"

**Nature's Anti-Inflammatory**

- "...reduce the inflammation and pain of arthritis, bursitis, tendinitis, neuritis, disc herniation, sprains and strains"
- "...effective relief of pain and swelling in human studies involving a variety of inflammatory conditions"
- "Effective All Natural Relief of Joint and Muscle Inflammation"

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for these products (including the use of the term "Anti-Inflammatory" in the name of the product "Nature's Anti-Inflammatory") suggest that they are intended to treat, prevent, cure, or mitigate

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Page 2 - Dr. James Meschino

diseases, namely various inflammatory diseases and conditions. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

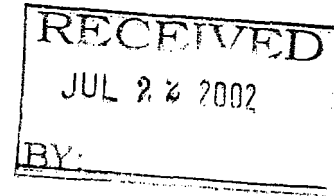
Director  
Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling  
and Dietary Supplements  
Center for Food Safety  
and Applied Nutrition

Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of  
Enforcement, HFC-200

FDA, Philadelphia District Office, Office of Compliance, HFR-MA140



July 18, 2002

Division of Compliance and Enforcement  
Office of Nutritional Products, Labeling and Dietary Supplements  
US Food & Drug Administration  
5100 Paint Branch Parkway  
College Park, MD 20740

Via Courier

Dear Sirs:

Please find enclosed copies of labels for a line of dietary supplements we have recently begun to distribute.

These labels each contain statements allowed for under section **403** (r) (6) of the Federal Food, Drug, & Cosmetic Act.

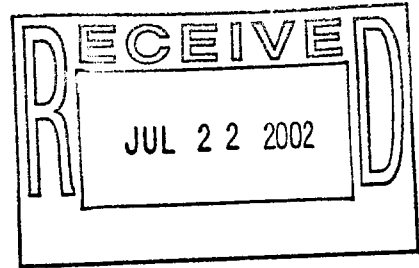
As President of this company, I hereby certify that the statements made are complete and accurate and our company has substantiation that the statements are truthful and not misleading.

Should you require any further information with regards to this matter, please contact me at (888) 251-1010 or by email, [jim@nutratherapeutics.com](mailto:jim@nutratherapeutics.com).

Sincerely yours,

Dr. James Meschino DC, MS.  
President, Nutra Therapeutics International

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**Suggested Supplementations:** Adults take one caplet three times daily with meals as a dietary supplement.

Nature's Anti-Inflammatory is a unique blend consisting of four powerful herbal agents that have been shown to reduce the inflammation and pain of arthritis, bursitis, tendinitis, neuritis, disc herniation, sprains and strains. These herbal ingredients have demonstrated effective relief of pain and swelling in human studies involving a variety of inflammatory conditions. These natural agents block the formation of inflammatory hormones known as prostaglandin 2 and do not cause irritation or erosion to the stomach or intestinal tract. Each herbal ingredient used in our formula is at the proper dosage and standardized grade shown to be effective in various studies.\*\*

Do not use if outer seal is broken or missing.  
Store in a cool, dry location. Keep out of reach of children.

\*\*The FDA has not evaluated this statement. This product is not intended to diagnose, treat, cure, or prevent disease.



## NUTRA THERAPEUTICS

*The Natural Choice of  
Healthcare Professionals*

### NATURE'S ANTI-INFLAMMATORY

- Effective All Natural Relief of Joint and Muscle Inflammation.\*\*
- With Curcumin & Boswellia

DIETARY SUPPLEMENT / 90 CAPLETS

## Supplement Facts

Serving Size 3 Caplets	Servings per Container 30	
	Amount Per Serving	Daily Value
Turmeric Extract (std. 95% Curcumin)	600 mg	*
Boswellia (std. 70% Boswellic Acids)	600 mg	*
White Willow Extract (std. 15% Salicin)	100 mg	*
Ginger Root Extract (std. 5% gingerols)	150 mg	*

\*Daily Value Not Established

Other Ingredients: Calcium Carbonate, Colloidal Silicon Dioxide, Microcrystalline Cellulose, Croscarmellose Sodium, Stearic Acid (vegetable source), Polydextrose.

Does not contain artificial preservatives, colors, flavors, or added sugar, corn, starch, milk products, egg, wheat, yeast, and is salt free.

Guaranteed quality, purity and potency.

Distributed by: Nutra Therapeutics International  
40 East Main Street, #168, Newark, DE 19711

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## ARTWORK APPROVAL

FAX APPROVAL TO #: 905-470-5450

ARTIST: AMANDA/# OF PAGES:

DATE: Sept 20101

CONTACT: BRUNO

CUSTOMER: MESCHINO

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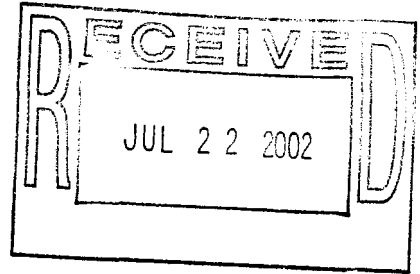
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1 CHANGE/REVISION  
CHANGES INDICATED: \_\_\_\_\_

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CANADIAN LABELS INC.

APPROVAL DATE: \_\_\_\_\_



**Suggested Supplementations:** Adults take one capsule three times daily with meals as a dietary supplement.

Glucosamine Joint Formula provides a pure and stabilized grade of glucosamine sulfate, MSM and natural anti-inflammatory agents that rebuild cartilage and control the low-grade inflammation of osteoarthritis and joint injuries.\*\*

This product contains the raw materials to help block the further destruction of osteoarthritic joints and regenerate damaged joint cartilage.\*\*

Our unique blend also provides proven, natural agents that help reduce the swelling and inflammation associated with chronic osteoarthritis and related joint injuries where cartilage damage is present, such as sports injuries.\*\*

Do not use if outer seal is broken or missing.  
Store in a cool, dry location. Keep out of reach of children.

\*\*The FDA has not evaluated this statement. This product is not intended to diagnose, treat, cure, or prevent disease.



## NUTRA THERAPEUTICS

*The Natural Choice of  
Healthcare Professionals*

# GLUCOSAMINE JOINT FORMULA

• WITH MSM •

• Advanced Formula for Relief and Repair of  
Arthritis and Cartilage Damage\* •

• With Anti-Inflammatory Herbs

DIETARY SUPPLEMENT / 90 CAPSULES

## Supplement Facts

Serving Size: 3 Capsules	Servings per Container: 30
	Amount Per Serving %Daily Value
Glucosamine Sulfate	1,500 mg *
MSM (Methyl Sulfonfyl Methane)	400 mg *
Quercetin	300 mg *
Bromelain	300 mg *
*Daily Value Not Established	

Other Ingredients: Stearic Acid (vegetable source) and gelatin.

Does not contain artificial preservatives, colors, flavors, or added sugar, corn, starch, milk products, egg, wheat, yeast, and is salt free.

• Guaranteed quality, purity and potency.

Distributed by: Nutra Therapeutics International  
40 East Main Street, #168, Newark, DE 19711

For research articles and education visit  
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## ARTWORK APPROVAL

FAX APPROVAL TOW: 905-470-5450

ARTIST: AMANDA / # OF PAGES:

DATE: Oct. 23/01

**CONTACT: BRUNO**

CUSTOMER: MESCHINO

FAX #: (905) 470-9074



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